IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Sällberg, et al.
Appl. No.	:	10/817,591
Filed	:	April 2, 2004
For	:	VACCINES CONTAINING RIBAVIRIN AND METHODS OF USE THEREOF
Examiner	:	Li, Bao Q.
Group Art Unit	:	1648

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Matti Sällberg declare and state as follows:

1. I am a co-inventor of the above-captioned patent application, co-founder and board member of Tripep AB, the assignee of the above-captioned patent application.

2. I received my Ph.D. from the Karolinska Institutet, Stockholm, Sweden in 1988. I have been an employee of Tripep AB since 1998. Since 2000, I have also held a position Karolinska Institutet as Professor of Biomedical Analysis. Currently, I oversee the research of several graduate students at the Karolinska Institutet and at Tripep AB in the field of virology and immunology. Throughout my career, I have authored or co-authored over 100 publications on the topic of viral immunology in peer reviewed scientific journals. I also participate in the peer-review process of several scientific journals in the fields of virology and immunology.

3. I have read and understand the Office Action mailed February 27, 2006 in connection with the above-referenced case.

4. As an expert in virology and immunology, I have extensive experience and knowledge concerning the identification and analysis of viral epitopes. As early as 1991, I began authoring publications relating to the antigenicity of various regions of hepatitis viruses, including analysis of immune responses to various hepatitis epitopes.

5. As of the earliest priority date, several viral epitopes, in particular epitopes as small as 8 consecutive amino acids of HCV NS3/4A, were known to those in the field of virology and immunology. This fact is illustrated by the teachings in WO 95/22317, hereinafter "Vitello et al.", published August 24, 1995, and WO 95/12667, hereinafter "LeRoux-Roels et al.", published May 11, 1995.

6. Vitello et al. describe several methods to identify and optimize CTL inducing peptides from many different viruses, including HCV, and the inventors note that CTL inducing peptides can be as small as 4 amino acids in length. Vitello et al. also provide techniques to optimize CTL peptides to length of 8-12acids, which are thought to be preferred lengths.

7. LeRoux-Roels et al. state that peptides of 8 contiguous amino acids of NS3 from HCV contain a T cell stimulating epitope, and these peptides can be used to prepare HCV immunogenic compositions. *See,* LeRoux-Roels et al., pages 5, 23, and 24. In particular, LeRoux-Roels et al. provide no less than 25 different antigenic peptides that contain 8 consecutive amino acids obtained from the HCV NS3 region spanning amino acid positions 1188 to 1463. *See, Id.,* pages 23 and 24. Accordingly, the field understood as of the spring and summer of 1995 that several peptides as short as 8 amino acids in length along the NS3/4A sequence were immunogenic.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By: _____ Date: 060630
Matti Sällberg, DDS, Ph.D.

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